EXHIBIT A

(Brief in Support of Plaintiffs' Motion to Stay)

Pfizer et al. v. Apotex et al.
Case No. 08 cv 7231

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DISTRICT

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC	)	
Plaintiffs,	)	FILED: DECEMBER 17, 2008 08 CV 7231 JUDGE DOW MAGISTRATE JUDGE ASHMAN AEE
v.	)	
APOTEX INC., and APOTEX CORP.,	)	
Defendants.	)	

COMPLAINT

Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company LLC, formerly Warner-Lambert Company, (collectively referred to as "Pfizer"), by their attorneys, for their complaint against Apotex Inc. and Apotex Corp. (collectively "Apotex"), allege as follows:

1. This is an action by Pfizer against Apotex for infringement of United States Letters Patent No. 5,273,995 ("the '995 patent"). A copy of the '995 patent is attached hereto as Exhibit A.

2. On December 28, 1993, the United States Patent and Trademark Office issued the '995 patent, entitled "[R-(R*R*)]-2-(4-Fluorophenyl)-β, δ-Dihydroxy-5-(1-Methylethyl-3-Phenyl-4-[(Phenylamino) Carbonyl]-1H-Pyrrole-1-Heptanoic Acid, Its Lactone Form And Salts Thereof", on an application filed by Bruce D. Roth and assigned to Warner-Lambert Company.

PARTIES, JURISDICTION AND VENUE

3. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

4. Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. Warner-Lambert Company has been the owner of record of the '995 patent since its issuance.

5. Warner-Lambert Company became a wholly owned subsidiary of Pfizer Inc effective June 19, 2000.

6. Warner-Lambert Company was converted into a Delaware limited liability company and changed its name to Warner-Lambert Company LLC on December 31, 2002. Warner-Lambert Company LLC has offices located at 235 East 42nd Street, New York, New York 10017.

7. Pfizer Ireland Pharmaceuticals is a partnership, organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

8. The exclusive licensee of the '995 patent is Pfizer Ireland Pharmaceuticals.

9. Pfizer holds an approved New Drug Application for an atorvastatin calcium formulation which it sells under the registered name Lipitor®.

10. The '995 patent is identified pursuant to 21 U.S.C. §355 (b)(1) by the United States Food and Drug Administration ("FDA") as covering Pfizer's Lipitor® product.

11. On information and belief, Defendant Apotex Inc. is a corporation operating and existing under the laws of Canada with its principal place of business at 150 Signet Drive, Weston, Ontario M9L 1T9 Canada.

12. On information and belief, Defendant Apotex Corp. ("Apotex USA") is a sister corporation of Apotex Inc. and is a corporation operating and existing under the laws of Delaware with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326 USA.

13. On information and belief, Apotex Inc. and/or Apotex USA filed with the FDA, in Rockville, Maryland, ANDA No. 90-548 under 21 U.S.C. §355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of atorvastatin calcium tablets in 10 mg, 20 mg, 40 mg and 80 mg dosage strengths, which are generic versions of Plaintiffs' Lipitor® products.

14. By letter dated November 4, 2008, Apotex Inc. notified Plaintiffs that it had filed an ANDA seeking FDA approval to market atorvastatin calcium tablets in 10 mg, 20 mg, 40 mg and 80 mg dosage strengths, and that it was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95 (c)(1).

15. The November 4, 2008 letter purported to contain an "Offer of Confidential Access to Application" pursuant to 21 U.S.C. § 355(j)(5)(C).

16. The purported "Offer of Confidential Access to Application" contained restrictions on the access and use of the information not contemplated or permitted by 21 U.S.C. § 355(j)(5)(C)(III).

17. This action arises under the Patent Laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338.

18. Apotex Inc. is subject to personal jurisdiction in this District.

19. Upon information and belief, Apotex USA is subject to personal jurisdiction in this District.

20. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391 (c), (d) and 1400 (b).

21. On information and belief, Apotex Inc. is in the business of developing and manufacturing generic pharmaceutical products.

22. On information and belief, Apotex Inc. sells and delivers its pharmaceutical products to Apotex USA in Florida.

23. On information and belief, Apotex USA is the agent, affiliate, representative, and/or alter ego of, and/or acts in concert with, Apotex Inc. for the purposes of marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Illinois.

24. On information and belief, Apotex USA, as the authorized agent of Apotex Inc. and/or in its own capacity, participated in the preparation and filing with the FDA of the Apotex ANDA for approval to market generic atorvastatin calcium in the United States.

25. In its November 4, 2008 letter, Apotex stated that the name and address of its agent in the United States authorized to accept service of process for Apotex for purposes of an infringement action based upon its November 4, 2008 letter is William A. Rakoczy, Rakoczy Molino Mazzochi Siwik LLP, 6 West Hubbard Street, Suite 500, Chicago, Illinois 60610.

26. By naming William A. Rakoczy as its agent Apotex has consented to jurisdiction in the State of Illinois for this action.

27. On information and belief, Apotex Inc. develops and manufactures generic drugs and, directly or indirectly through Apotex USA, markets, distributes, and sells its generic drugs throughout the United States, including the State of Illinois.

28. Personal jurisdiction over Apotex Inc. is proper also because it purposefully avails itself of the privilege of selling its generic products in the State of Illinois and can therefore reasonably expect to be subject to jurisdiction in Courts in Illinois. Among other things, upon information and belief, Apotex Inc., directly or through its sister corporation Apotex USA, places goods into the stream of commerce for distribution throughout the United States, including the State of Illinois.

29. Personal jurisdiction over Apotex USA is proper also because has purposely availed itself of the privilege of doing business in this State. Further, Apotex USA maintains continuous and systematic contacts with the State of Illinois so as to reasonably allow jurisdiction to be exercised over it.

30. An amended final judgment declaring claim 6 of the '995 patent invalid pursuant to the provisions of 35 U.S.C. § 112, ¶ 4 has been entered by the United States District Court for the District of Delaware in Civil Action No. 03-209-JJF, by Orders of the Court dated November 7, 2006 and November 30, 2006 (D.I. 338 and 344). A copy of the final judgment, as amended, is attached as Exhibit B. No relief is sought herein pursuant to claim 6 of the '995 patent.

FIRST CLAIM FOR RELIEF;
INFRINGEMENT OF THE '995 PATENT

31. Pfizer realleges paragraphs 1 through 30 above as if fully set forth herein.

32. Pfizer has received a letter dated November 4, 2008 from Apotex (the "November 4, 2008 letter") which notified Pfizer that Apotex had filed an Abbreviated New Drug Application (ANDA No. 90-548), seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product containing atorvastatin calcium prior to the expiration of the '995 patent. A copy of the November 4, 2008 letter is attached hereto as Exhibit C.

33. The expiration date for the '995 patent is December 28, 2010.

34. Lipitor® was granted a further period of exclusivity under section 505 of the Food, Drug and Cosmetic Act to June 28, 2011.

35. Apotex has infringed the '995 patent under 35 U.S.C. 271 (e)(2) by filing Apotex's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing atorvastatin calcium prior to the expiration of the '995 patent.

36. Pfizer will be irreparably harmed if Apotex is not enjoined from infringing the '995 patent.

WHEREFORE, Pfizer requests the following relief:

A. A judgment providing that pursuant to 35 U.S.C. §271 (e) (4) (A), the effective date of any FDA approval for Apotex's ANDA No. 90-548 be no earlier than June 28, 2011, the date of expiration of the '995 Patent including the period of exclusivity granted to Lipitor® under section 505 of the Food, Drug and Cosmetic Act;

B. A judgment pursuant to 35 U.S.C. §271 (e) (4) (B) permanently enjoining Apotex, each of its officers, agents, servants, employees and attorneys, and those persons

in active concert or participation with it or any of them, from making, using, selling, offering to sell, or importing the atorvastatin calcium product described in Apotex's ANDA 90-548 until June 28, 2011, the expiration date of the '995 patent including the period of exclusivity granted to Lipitor® under section 505 of the Food, Drug and Cosmetic Act;

C. Attorneys' fees in this action under 35 U.S.C. §285;

D. Costs and expenses in this action; and

E. Such further and other relief as this Court may deem just and proper.

RESPECTFULLY SUBMITTED,

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EXHIBIT B

(Brief in Support of Plaintiffs' Motion to Stay)

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC, Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 1:08-07231 Judge Robert M. Dow Jr. Magistrate Judge Martin C. Ashman

ANSWER, DEFENSES, COUNTERCLAIM AND JURY DEMAND OF DEFENDANTS APOTEX INC. AND APOTEX CORP.

Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") hereby answer the Complaint of Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company LLC, and Warner-Lambert Company (collectively referred to as "Pfizer")—for which every allegation not expressly admitted is denied—as follows:

1. This is an action by Pfizer against Apotex for infringement of United States Letters Patent No. 5,273,995 ("the '995 patent"). A copy of the '995 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that this action purports to assert alleged infringement of U.S. Patent No. 5,273,995 ("the '995 patent"), and that what purports to be a copy of the '995 patent is attached to the Complaint as Exhibit A. Apotex denies that the Court has subject matter jurisdiction for any such claim. Apotex denies the remaining allegations of Paragraph 1.

2. On December 28, 1993, the United States Patent and Trademark Office issued the '995 patent, entitled "[R-(R*R*)]-2-(4-Fluorophenyl)-β, δ-Dihydroxy-5-(1-Methylethyl-3-Phenyl-4-[(Phenylamino) Carbonyl]-1H-Pyrrole-l-Heptanoic Acid, Its Lactone Form And Salts Thereof", on an application filed by Bruce D. Roth and assigned to Warner-Lambert Company.

ANSWER: Apotex admits that, according to the electronic records of the United States Patent and Trademark Office ("USPTO"), on or about December 28, 1993, the USPTO issued the '995 patent, entitled "[R-(R*R*)]-2-(4-Fluorophenyl)-β, δ-Dihydroxy-5-(1-Methylethyl-3-Phenyl-4-[(Phenylamino) Carbonyl]-1H-Pyrrole-l-Heptanoic Acid, Its Lactone Form And Salts Thereof," to Bruce D. Roth, and that the cover page of the '995 patent identifies "Warner-Lambert Company" as the "assignee." Apotex denies the remaining allegations of Paragraph 2.

PARTIES, JURISDICTION AND VENUE

3. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies all such allegations.

4. Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. Warner-Lambert Company has been the owner of record of the '995 patent since its issuance.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4, and therefore denies all such allegations.

5. Warner-Lambert Company became a wholly owned subsidiary of Pfizer Inc. effective June 19, 2000.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5, and therefore denies all such allegations.

6. Warner-Lambert Company was converted into a Delaware limited liability company and changed its name to Warner-Lambert Company LLC on December 31, 2002.

Warner-Lambert Company LLC has offices located at 235 East 42nd Street, New York, New York 10017.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6, and therefore denies all such allegations.

7. Pfizer Ireland Pharmaceuticals is a partnership, organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7, and therefore denies all such allegations.

8. The exclusive licensee of the '995 patent is Pfizer Ireland Pharmaceuticals.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8, and therefore denies all such allegations.

9. Pfizer holds an approved New Drug Application for an atorvastatin calcium formulation which it sells under the registered name Lipitor®.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that the electronic version of the U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies "PFIZER" as the "applicant" for New Drug Application ("NDA") No. 20-702 for LIPITOR® (Atorvastatin Calcium) Tablets. Apotex denies the remaining allegations of Paragraph 9.

10. The '995 patent is identified pursuant to 21 U.S.C. §355 (b)(1) by the United States Food and Drug Administration ("FDA") as covering Pfizer's Lipitor® product.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that the electronic Orange Book lists the '995 patent in connection with NDA No. 20-702 for LIPITOR® (Atorvastatin Calcium) Tablets. Apotex denies the remaining allegations of Paragraph 10.

11. On information and belief, Defendant Apotex Inc. is a corporation operating and existing under the laws of Canada with its principal place of business at 150 Signet Drive, Weston, Ontario M9L 1T9 Canada.

ANSWER: Apotex admits that Apotex Inc. is a corporation existing solely under the laws of Canada with its only places of business located in Canada, including at 150 Signet Drive, Weston, Ontario M9L 1T9, Canada. Apotex denies the remaining allegations of Paragraph 11.

12. On information and belief, Defendant Apotex Corp. ("Apotex USA") is a sister corporation of Apotex Inc. and is a corporation operating and existing under the laws of Delaware with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326 USA.

ANSWER: Apotex admits that Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex denies the remaining allegations of Paragraph 12. Apotex further denies that Apotex Corp. is a proper party to this suit, and also denies that the Court has subject matter jurisdiction for any claims asserted against Apotex Corp.

13. On information and belief, Apotex Inc. and/or Apotex USA filed with the FDA, in Rockville, Maryland, ANDA No. 90-548 under 21 U.S.C. §355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of atorvastatin calcium tablets in 10 mg, 20 mg, 40 mg and 80 mg dosage strengths, which are generic versions of Plaintiffs' Lipitor® products.

ANSWER: Apotex admits that Apotex Inc. has filed with the FDA in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Apotex denies the remaining allegations of Paragraph 13. Apotex further denies that Apotex Corp. filed any such ANDA, denies that Apotex Corp. is a proper party to this suit, and also denies that the Court has subject matter jurisdiction for any claims asserted against Apotex Corp.

14. By letter dated November 4, 2008, Apotex Inc. notified Plaintiffs that it had filed an ANDA seeking FDA approval to market atorvastatin calcium tablets in 10 mg, 20 mg, 40 mg

and 80 mg dosage strengths, and that it was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95 (c)(1).

ANSWER: Apotex admits that, in a letter dated November 4, 2008, Apotex Inc. provided Pfizer with the requisite notice of Apotex Inc.'s ANDA for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg, together with the detailed factual and legal bases for Apotex Inc.'s "paragraph IV certification" to the '995 patent, and that such notice satisfied all statutory and regulatory requirements. Apotex denies the remaining allegations of Paragraph 14.

15. The November 4, 2008 letter purported to contain an "Offer of Confidential Access to Application" pursuant to 21 U.S.C. § 355(j)(5)(C).

ANSWER: Apotex admits that Apotex Inc.'s notice letter, dated November 4, 2008, contains an Offer of Confidential Access to Application under 21 U.S.C. § 355(j)(5)(C), and that such offer satisfies all statutory requirements. Apotex denies the remaining allegations of Paragraph 15.

16. The purported "Offer of Confidential Access to Application" contained restrictions on the access and use of the information not contemplated or permitted by 21 U.S.C. § 355()(5)(C)(III).

ANSWER: Denied.

17. This action arises under the Patent Laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338.

ANSWER: Denied.

18. Apotex Inc. is subject to personal jurisdiction in this District.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, to conserve the resources of the parties and the Court, Apotex Inc. does not contest personal jurisdiction in this judicial district for purposes of this action only.

19. Upon information and belief, Apotex USA is subject to personal jurisdiction in this District.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, to conserve the resources of the parties and the Court, Apotex Corp. does not contest personal jurisdiction in this judicial district for purposes of this action only.

20. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391 (c), (d) and 1400 (b).

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, to conserve the resources of the parties and the Court, Apotex does not contest venue in this judicial district for purposes of this action only.

21. On information and belief, Apotex Inc. is in the business of developing and manufacturing generic pharmaceutical products.

ANSWER: Admitted.

22. On information and belief, Apotex Inc. sells and delivers its pharmaceutical products to Apotex USA in Florida.

ANSWER: Denied.

23. On information and belief, Apotex USA is the agent, affiliate, representative, and/or alter ego of, and/or acts in concert with, Apotex Inc. for the purposes of marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Illinois.

ANSWER: Denied.

24. On information and belief, Apotex USA, as the authorized agent of Apotex Inc. and/or in its own capacity, participated in the preparation and filing with the FDA of the Apotex ANDA for approval to market generic atorvastatin calcium in the United States.

ANSWER: Denied.

25. In its November 4, 2008 letter, Apotex stated that the name and address of its agent in the United States authorized to accept service of process for Apotex for purposes of an

infringement action based upon its November 4, 2008 letter is William A. Rakoczy, Rakoczy Molino Mazzochi Siwik LLP, 6 West Hubbard Street, Suite 500, Chicago, Illinois 60610.

ANSWER: Apotex admits that, in Apotex Inc.'s letter dated November 4, 2008, and as required by FDA regulations, Apotex Inc. identified its outside litigation counsel at Rakoczy Molino Mazzochi Siwik LLP, 6 West Hubbard Street, Suite 500, Chicago, Illinois 60610, as the agent in the United States authorized to accept service of process for Apotex Inc. for purposes of an infringement action based upon Apotex Inc.'s notice letter. Apotex denies the remaining allegations of Paragraph 25.

26. By naming William A. Rakoczy as its agent Apotex has consented to jurisdiction in the State of Illinois for this action.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for purposes of this action only.

27. On information and belief, Apotex Inc. develops and manufactures generic drugs and, directly or indirectly through Apotex USA, markets, distributes, and sells its generic drugs throughout the United States, including the State of Illinois.

ANSWER: Denied.

28. Personal jurisdiction over Apotex Inc. is proper also because it purposefully avails itself of the privilege of selling its generic products in the State of Illinois and can therefore reasonably expect to be subject to jurisdiction in Courts in Illinois. Among other things, upon information and belief, Apotex Inc., directly or through its sister corporation Apotex USA, places goods into the stream of commerce for distribution throughout the United States, including the State of Illinois.

ANSWER: Denied. Further answering, to conserve the resources of the parties and the Court, Apotex Inc. does not contest personal jurisdiction in this judicial district for purposes of this action only.

29. Personal jurisdiction over Apotex USA is proper also because has [sic] purposely availed itself of the privilege of doing business in this State. Further, Apotex USA maintains

continuous and systematic contacts with the State of Illinois so as to reasonably allow jurisdiction to be exercised over it.

ANSWER: Denied. Apotex further denies that Apotex Corp. is a proper party to this suit, and also denies that the Court has subject matter jurisdiction for any claims asserted against Apotex Corp. Further answering, to conserve the resources of the parties and the Court, Apotex Corp. does not contest personal jurisdiction in this judicial district for purposes of this action only.

30. An amended final judgment declaring claim 6 of the '995 patent invalid pursuant to the provisions of 35 U.S.C. § 112, ¶ 4 has been entered by the United States District Court for the District of Delaware in Civil Action No. 03-209-JJF, by Orders of the Court dated November 7, 2006 and November 30, 2006 (D.I. 338 and 344). A copy of the final judgment, as amended, is attached as Exhibit B. No relief is sought herein pursuant to claim 6 of the '995 patent.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that the United States Court of Appeals for the Federal Circuit held that claim 6 of the '995 patent is invalid, that the United States District Court for the District of Delaware entered a final judgment of invalidity against Pfizer based on that decision, and that what purports to be a copy of that final judgment is attached as Exhibit B to the Complaint. Apotex denies the remaining allegations of Paragraph 30.

FIRST CLAIM FOR RELIEF;
INFRINGEMENT OF THE '995 PATENT

31. Pfizer realleges paragraphs 1 through 30 above as if fully set forth herein.

ANSWER: Apotex realleges its answers to paragraphs 1 through 30 above as if fully set forth herein.

32. Pfizer has received a letter dated November 4, 2008 from Apotex (the "November 4, 2008 letter") which notified Pfizer that Apotex had filed an Abbreviated New Drug Application (ANDA No. 90-548), seeking approval from FDA to engage in the commercial manufacture, use, and sale of a product containing atorvastatin calcium prior to the expiration of the '995 patent. A copy of the November 4, 2008 letter is attached hereto as Exhibit C.

ANSWER: Apotex admits that, in a letter dated November 4, 2008, Apotex Inc. provided Pfizer with the requisite notice of Apotex Inc.'s ANDA seeking FDA approval for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg, prior to the expiration of the '995 patent, and that what purports to be a copy of such notice is attached as Exhibit C to the Complaint. Apotex denies the remaining allegations of Paragraph 32.

33. The expiration date for the '995 patent is December 28, 2010.

ANSWER: Denied.

34. Lipitor® was granted a further period of exclusivity under section 505 of the Food, Drug and Cosmetic Act to June 28, 2011.

ANSWER: Denied.

35. Apotex has infringed the '995 patent under 35 U.S.C. 271 (e)(2) by filing Apotex's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing atorvastatin calcium prior to the expiration of the '995 patent.

ANSWER: Denied.

36. Pfizer will be irreparably harmed if Apotex is not enjoined from infringing the '995 patent.

ANSWER: Denied.

* * *

Apotex denies every allegation not expressly admitted herein. Apotex further denies that Pfizer is entitled to any of the relief requested, or to any relief whatsoever. Apotex demands judgment dismissing Pfizer's Complaint with prejudice, awarding Apotex attorneys' fees and costs incurred defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just.

DEFENSES

Without undertaking any of the burdens imposed by law on Plaintiffs, and without admitting any of the allegations in the Complaint not otherwise admitted, Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") assert the following defenses:

First Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Defense

The manufacture, use, sale, offer for sale, or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if made, imported, or marketed, infringe any valid and/or enforceable claim of United States Patent No. 5,273,995 ("the '995 patent").

Third Defense

The claims of the '995 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

Fourth Defense

Apotex has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and/or enforceable claim of the '995 patent.

Fifth Defense

The Court lacks subject matter jurisdiction for any claim of alleged infringement of the '995 patent.

Sixth Defense

The '995 patent has been and/or must be surrendered, and thus is unenforceable as a matter of law against Apotex and others.

Seventh Defense

The Court lacks subject matter jurisdiction for any claims asserted against Apotex Corp.

Eighth Defense

Apotex Corp. is not a proper party to this suit.

Ninth Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIM

Defendants/Counterclaim-Plaintiffs, Apotex Inc. and Apotex Corp. (collectively, "Apotex"), for their Counterclaim against Plaintiffs/Counterclaim-Defendants, Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company LLC, and Warner-Lambert Company (collectively referred to as "Pfizer"), allege as follows:

Nature Of The Action

1. Apotex brings—and is entitled by statute to maintain—this counterclaim for declaratory judgment of patent non-infringement and/or invalidity under, *inter alia*, the Declaratory Judgment Act and 21 U.S.C. § 355(j)(5)(C)(i), which is part of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA").

2. This action arises out of, *inter alia*, Apotex Inc.'s submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking

approval to market a generic version of Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg, which Pfizer currently markets under the brand-name LIPITOR®.

3. Pfizer purports to own, and to have the right to enforce, among others, U.S. Patent Nos. 5,273,995 ("the '995 patent"); 5,686,104 ("the '104 patent"); 5,969,156 ("the '156 patent"); and 6,126,971 ("the '971 patent"), true and accurate copies of which are attached hereto as Exhibits A-D, respectively (collectively, "the patents-in-suit").

4. Upon submission by Pfizer, the patents-in-suit were listed in the FDA's so-called "Orange Book," a compilation of approved drugs. As a consequence of such listing, Pfizer maintains, and has affirmatively represented to the world, that the patents-in-suit claim the approved drug, LIPITOR®, or a method of using that drug, and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including Apotex Inc., attempting to market a generic atorvastatin product before patent expiration. Moreover, Pfizer has enforced and continues to vigorously enforce its intellectual property rights on drugs against Apotex and other generic pharmaceutical companies. In fact, Pfizer already has sought to enforce the '995 patent against numerous companies seeking to market a generic atorvastatin product prior to the expiration of the '995 patent. Pfizer has already sued Apotex for alleged infringement of the '995 patent in at least two districts. On information and belief, Pfizer also filed actions against Ranbaxy, Teva and Cobalt alleging infringement of the '995 patent.

5. As required by statute and regulation, Apotex Inc. has certified to FDA that Apotex Inc.'s ANDA product will not infringe the patents-in-suit and/or that such patents are invalid and/or unenforceable, and has further notified Pfizer of the legal and factual bases for that certification. Apotex Inc.'s submission of this so-called "paragraph IV certification" purportedly constitutes an artificial act of patent infringement putting Apotex at considerable risk of being

sued by Pfizer both before and after market entry. Indeed, this regulatory submission created the purported subject matter jurisdiction for Pfizer to sue Apotex for alleged infringement of the '995 patent and others. It likewise created the necessary case or controversy for Apotex to file and maintain a counterclaim for declaratory judgment of patent non-infringement and/or invalidity.

6. Pfizer has already created a substantial controversy by suing Apotex for alleged infringement of the '995 patent. There is an actual, substantial, and continuing justiciable case and controversy between Apotex and Pfizer regarding infringement of the remaining patents-in-suit as well, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

7. Apotex is entitled by law to bring and maintain this action for declaratory judgment of patent non-infringement and/or invalidity under the Declaratory Judgment Act and the MMA where, as here, Pfizer did not sue Apotex Inc. within 45 days of receipt of Apotex Inc.'s notice of paragraph IV certification to the remaining patents-in-suit, and Apotex Inc. has offered Pfizer an Offer of Confidential Access to Apotex Inc.'s ANDA for generic atorvastatin tablets.

8. Apotex is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Apotex Inc.'s proposed generic atorvastatin product does not and will not infringe the patents-in-suit, and/or that such patents are invalid. Absent the exercise of jurisdiction by this Court and such declaratory relief, Apotex and the American public will be irreparably harmed by the indefinite delay in the market entry and availability of lower-priced generic atorvastatin.

The Parties

9. Defendant/Counterclaim-Plaintiff Apotex Inc. is a corporation organized and existing solely under the laws of Canada and having its only places of business in Canada.

10. Defendant/Counterclaim-Plaintiff Apotex Corp. is a Delaware corporation with offices in Florida.

11. Upon information and belief, Plaintiff/Counterclaim-Defendant Pfizer Inc. purports to be a corporation organized and existing under the laws of the State of Delaware with a place of business at 235 East 42nd Street, New York, New York 10017.

12. Upon information and belief, Plaintiff/Counterclaim-Defendant Warner-Lambert Company purports to be a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017.

13. Upon information and belief, Plaintiff/Counterclaim-Defendant Warner-Lambert Company LLC purports to be a Delaware limited liability company with offices located at 235 East 42nd Street, New York, New York 10017.

14. Upon information and belief, Plaintiff/Counterclaim-Defendant Pfizer Ireland Pharmaceuticals purports to be a partnership, organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland.

15. Pfizer Inc., Warner-Lambert Company, Warner-Lambert Company LLC and Pfizer Ireland Pharmaceuticals will hereinafter be referred to collectively in this Counterclaim as "Pfizer." On information and belief, Pfizer conducts substantial business in the United States and in this District through its various agents, affiliates, representatives, subsidiaries and/or alter egos.

Jurisdiction And Venue

16. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the MMA, 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

17. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because it involves substantial claims arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*; under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because it is an actual controversy concerning the infringement of the patents-in-suit; and under the MMA, 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5), because Congress has directed that district courts maintain and exercise jurisdiction in such cases.

18. There exists a substantial and continuing actual, justiciable case or controversy between Apotex and Pfizer regarding infringement of the patents-in-suit.

19. This Court can and should declare the rights and legal relations of the parties regarding non-infringement and/or invalidity of the patents-in-suit pursuant to, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the MMA, 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

20. Apotex has the statutory right to bring and maintain this declaratory judgment action under 21 U.S.C. § 355(j)(5)(C)(i). This Court can and should exercise its declaratory judgment jurisdiction over Apotex's claims pursuant to 35 U.S.C. § 271(e)(5).

21. This Court has personal jurisdiction over Pfizer because, *inter alia*, Pfizer conducts substantial business in, and has regular and systematic contact with, this District, and because Pfizer has purposefully availed itself of the rights and privileges of this forum by suing Apotex in this District.

22. Venue is proper in this District under 28 U.S.C. § 1400(b). Venue is also proper in this District under 28 U.S.C. §§ 1391 because, *inter alia*, Pfizer is subject to personal jurisdiction in this District.

Background

I. Statutory Scheme For Approval Of New And Generic Drugs.

23. The approval of new and generic drugs is governed by the applicable provisions of the FFDCA, 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and amended again by the MMA (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271).

B. New/previously-unapproved drugs and patent listing requirements.

24. Before marketing an original new or previously-unapproved drug in the United States, the FFDCA, as amended by Hatch-Waxman and the MMA, requires that an applicant submit, and that the FDA approve, a new drug application ("NDA") under 21 U.S.C. § 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling relating to the use of the drug for which approval is requested.

25. An NDA applicant is required, within its NDA, to submit information (*e.g.*, the patent number and expiration date) regarding each patent that claims the drug or method of using the drug that is the subject of the NDA and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product. 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2).

26. The FDA publishes patent information submitted by an NDA-holder in the Patent and Exclusivity Information Addendum of the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

27. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder/patent owner, by law, necessarily maintains that the listed patent claims the approved NDA drug, or a method of using that drug, and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use, or sale of the drug, and, in particular, against any company that is seeking to make a generic bioequivalent version of the NDA drug before patent expiration.

28. Thus, the NDA-holder/patent owner necessarily puts all prospective generic ANDA applicants on notice that a suit for infringement can and will be asserted against any ANDA applicant that attempts to seek approval for and market a generic version of the NDA drug before patent expiration.

29. Such conduct by the NDA-holder/patent owner gives rise to a reasonable apprehension on the generic applicant's part that it will face an infringement suit, or the threat of one, if it attempts to seek approval for or to market a generic version of the NDA drug before patent expiration.

C. Generic drugs and patent certification requirements.

30. The FFDCA, as amended by Hatch-Waxman and the MMA, provides for an ANDA approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-priced generic versions of previously approved brand-name or NDA drugs on an expedited basis, thereby benefiting the U.S. health-care system and American consumers. The ANDA process is a streamlined version of the full NDA procedure and results in a generic drug product that is normally marketed under the chemical name of the active drug ingredient.

31. An applicant may invoke this procedure for expedited FDA approval of a generic version of an already-approved NDA drug by submitting an ANDA to the FDA under 21 U.S.C. § 355(j).

32. Instead of repeating the clinical studies of safety and efficacy conducted for the previously-approved NDA drug, a generic applicant submitting an ANDA is required to establish, among other details, that its proposed generic product is bioequivalent to the already-approved NDA drug (*i.e.*, has no significant difference in rate and extent of absorption). 21 U.S.C. § 355(j)(2)(A).

33. An ANDA applicant also is required to address each patent properly listed in the Orange Book in connection with the approved NDA drug. In particular, with certain exceptions not applicable here, Hatch-Waxman requires an ANDA applicant to submit one of four types of patent certifications for each properly listed patent: (I) that the NDA-holder/patent owner has not submitted any patent information to the FDA; (II) that the listed patent has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its product until after the expiration date (commonly referred to as a "paragraph III certification"); or, (IV) that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted (commonly referred to as a "paragraph IV certification"). 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(IV). This last type of certification, a paragraph IV certification, signifies that the generic ANDA applicant intends to market its generic product prior to expiration of the subject patent. Such certification constitutes an artificial act of patent infringement that gives rise to subject matter jurisdiction for any declaratory judgment action on that patent. 35 U.S.C. § 271(e).

34. When an ANDA applicant submits a paragraph IV certification for a listed patent, the generic applicant must notify the NDA-holder/patent owner that it has filed an ANDA to obtain regulatory approval of a generic version of the NDA drug, and that the ANDA contains a paragraph IV certification for a listed patent (indicating that the ANDA applicant intends to market its generic product before expiration of the listed patent). 21 U.S.C. § 355(j)(2)(B). This notice contains a detailed statement of the factual and legal bases for the ANDA applicant's certification that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic applicant's generic drug product. 21 U.S.C. § 355(j)(2)(B)(iv).

35. The submission of a paragraph IV certification has two important consequences.

36. First, an applicant that is first to submit an ANDA containing a paragraph IV certification for a listed patent is entitled to 180 days of generic marketing exclusivity during which no other ANDA for that drug product will be approved, except as set forth below. 21 U.S.C. § 355(j)(5)(B)(iv).

37. Second, the submission of a paragraph IV certification for a listed patent constitutes an artificial act of infringement that creates the necessary case or controversy and subject matter jurisdiction to enable an NDA-holder/patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

38. The submission of a paragraph IV certification likewise creates the necessary case or controversy and subject matter jurisdiction for an ANDA applicant to file a declaratory judgment action against the NDA-holder/patent owner if the ANDA applicant is not sued within the applicable 45-day period, as set forth below.

39. Upon receiving notice of a paragraph IV certification for a listed patent submitted by an ANDA applicant, the NDA-holder/patent owner may file suit for infringement of the listed patent under 35 U.S.C. § 271(e)(2)(A) within 45 days of receiving such notification. Such a suit automatically delays the FDA from issuing final approval of the ANDA for up to thirty (30) months. 21 U.S.C. § 355(j)(5)(B)(iii). An ANDA applicant is statutorily prohibited from seeking a declaratory judgment during the 45-day period in which the NDA-holder/patent owner may bring suit after receiving notification of the ANDA and paragraph IV certification. *Id.*

40. If the NDA-holder/patent owner does not file such a suit, the ANDA applicant can file and maintain a suit for declaratory judgment against the NDA-holder/patent owner to obtain patent certainty. Indeed, as explained below, Congress explicitly mandated that an ANDA-filer is entitled to maintain a declaratory judgment action when it is not sued. 21 U.S.C. § 355(j)(5)(C).

41. Congress enacted Hatch-Waxman and the ANDA approval process in order to expedite the marketing of lower-priced generic drug products. Congress intended that the generic manufacturing and marketing of a drug should be allowed as soon as it is determined that the particular generic drug does not violate patent rights. Congress also determined that full generic competition would not be delayed indefinitely by the 180-day exclusivity period.

II. Congress Explicitly Mandated That An ANDA-Filer May Bring And Maintain A Declaratory Judgment Action When The Brand Company Does Not Bring An Infringement Action.

42. On December 8, 2003, the MMA was signed into law. Title XI of the MMA, labeled "Access to Affordable Pharmaceuticals," amended provisions of the FFDCA and, in particular, Hatch-Waxman.

43. Under the MMA, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain an action for declaratory judgment against an

NDA-holder/patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder/patent owner brought an action for infringement of the patent within the 45-day period; and, (3) the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

44. Once these three conditions are met, the MMA specifically and unequivocally provides that an ANDA applicant "may, in accordance with section 2201 of Title 28 [of the United States Code], bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II).

45. An ANDA applicant may exercise its right to file and maintain a declaratory judgment action under the MMA regardless of whether or not the Offer of Confidential Access to Application is accepted.

46. The new declaratory judgment provision contained in the MMA, Section 1101 of the MMA, 117 Stat. 2066, 2454-2456, applies to all ANDAs pending on or after December 8, 2003, which includes these proceedings.

47. Congress' intent in amending 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5) was to extend to ANDA applicants, like Apotex Inc. here, the right to file and maintain a declaratory judgment action for patent non-infringement and/or invalidity against an NDA-holder/patent owner, and grant the court subject matter jurisdiction in such an action.

48. The purpose of this provision was two-fold. The first purpose was to allow generic applicants to obtain patent certainty before marketing their generic products.

49. The second purpose was to allow generic applicants to obtain court decisions that would expedite the introduction of generic drugs and clear up any bottleneck in the market created by another applicant's 180-day exclusivity.

III. Patents-In-Suit.

50. Upon information and belief, on or about December 28, 1993, the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 5,273,995 ("the '995 patent"), entitled "[R-(R*R*)]-2-(4-Fluorophenyl)-β, δ-Dihydroxy-5-(1-Methylethyl-3-Phenyl-4-[(Phenylamino) Carbonyl]-1H-Pyrrole-l-Heptanoic Acid, Its Lactone Form And Salts Thereof," to Bruce D. Roth. A true and correct copy of the '995 patent is attached hereto as Exhibit A.

51. Upon information and belief, on or about November 11, 1997, the USPTO issued U.S. Patent No. 5,686,104 ("the '104 patent"), entitled "Stable Oral CI-981 Formulation and Process of Preparing Same," to Nancy Mills, Nouman A. Muhammad, Jay Weiss, and Russell U. Nesbitt. A true and correct copy of the '104 patent is attached hereto as Exhibit B.

52. Upon information and belief, on or about October 19, 1999, the USPTO issued U.S. Patent No. 5,969,156 ("the '156 patent"), entitled "Crystalline [R-(R*,R*)]-2-(4-Fluorophenyl)-β,δ-Dihydroxy-5-(1-Methylethyl)-3-Phenyl-4-[(Phenylamino)Carbonyl]-1H-Pyrrole-1-Heptanoic Acid Hemi Calcium Salt (Atorvastatin)," to Christopher A. Briggs, Rex A. Jennings, Robert Wade, Kikuko Harasawa, Shigeru Ichikawa, Kazuo Minohara, and Shinsuke Nakagawa. A true and correct copy of the '156 patent is attached hereto as Exhibit C.

53. Upon information and belief, on or about October 3, 2000, the USPTO issued U.S. Patent No. 6,126,971 ("the '971 patent"), entitled "Stable Oral CI-981 Formulation and Process For Preparing Same," to Nancy Mills, Nouman A. Muhammad, Jay Weiss, and Russell U. Nesbitt. A true and correct copy of the '971 patent is attached hereto as Exhibit D.

54. Upon information and belief, Pfizer purports and claims to own, and to have the right to enforce, the '995, '104, '156, and '971 patents.

IV. Pfizer's LIPITOR® (Atorvastatin).

55. Pfizer purports to be the holder of approved NDA No. 20-702 for LIPITOR® (atorvastatin calcium) tablets, 10 mg, 20 mg, 40 mg, and 80 mg.

56. The FDA approved LIPITOR® in 1996. Today, LIPITOR® remains the only atorvastatin product on the market. On information and belief, Pfizer claims that LIPITOR® has generated billions of dollars in revenues for Pfizer in the U.S.

57. Pfizer submitted information on the patents-in-suit to the FDA for listing in the Orange Book. By virtue of that submission, the FDA listed the patents-in-suit in the Orange Book in connection with Pfizer's approved NDA for LIPITOR® (atorvastatin) tablets.

58. By listing the patents-in-suit in the Orange Book, Pfizer maintains, and has affirmatively represented to the world, that the patents-in-suit claim LIPITOR® (atorvastatin) tablets, or a method of using that drug, and that an infringement suit could reasonably be asserted against any generic ANDA applicant, including Apotex Inc., that attempts to seek approval for, and market, a generic version of atorvastatin before patent expiration.

59. The listing of the patents-in-suit in the Orange Book alone objectively creates the necessary case or controversy and subject matter jurisdiction for an ANDA-filer to file and maintain a declaratory judgment action if it is not sued by Pfizer within the requisite 45-day period for infringement of any of the patents-in-suit.

V. Apotex's ANDA For Atorvastatin.

60. Apotex Inc. has submitted an ANDA to the FDA seeking approval to market a generic version of atorvastatin calcium tablets 10 mg, 20 mg, 40 mg, and 80 mg.

61. Apotex Inc. devoted considerable resources researching, developing, and testing its generic atorvastatin product, all toward compiling the information necessary to submit its ANDA for generic atorvastatin tablets.

62. Apotex Inc.'s ANDA included and contains a paragraph IV certification to the patents-in-suit, stating that such patents will not be infringed by the manufacture, use, offer for sale, sale, or importation of Apotex Inc.'s generic atorvastatin tablets and/or that such patents are invalid and/or unenforceable. This certification signified that Apotex Inc. seeks approval of its generic atorvastatin product prior to expiration of the patents-in-suit.

63. Apotex Inc.'s ANDA is substantially complete and was accepted for filing by the FDA.

64. In accordance with 21 U.S.C. §§ 355(j)(2)(B), Apotex Inc. provided Pfizer with the requisite notice that it submitted an ANDA and a paragraph IV certification to the patents-in-suit. This notice included a detailed statement setting forth the factual and legal bases why the patents-in-suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of Apotex Inc.'s generic atorvastatin tablets, and/or that such patents are invalid and/or unenforceable.

65. Upon receipt of Apotex Inc.'s notice of paragraph IV certification, Pfizer sued Apotex in this District, and in the United States District Court for the District of Delaware, alleging infringement of the '995 patent under 21 U.S.C. § 271(e)(2)(A).

66. Pfizer did not sue Apotex for infringement of the '104, '156, and '971 patents within the 45-day period for instituting an infringement suit under 21 U.S.C. § 271(e). Pfizer, however, still retains the ability to do so.

VI. Apotex's Offer Of Confidential Access To Application.

67. Apotex Inc.—by letter and as required under 21 U.S.C. § 355(j)(5)(C)—extended to Pfizer an Offer of Confidential Access to Application to access certain information in Apotex Inc.'s ANDA for atorvastatin tablets.

68. By providing this Offer of Confidential Access to Application, and because Pfizer did not sue Apotex within 45 days of receipt of Apotex's notice of paragraph IV certification, Apotex is statutorily entitled to file and maintain a declaratory judgment action against Pfizer under 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C).

VII. Pfizer's Litigious Conduct And Vigorous Enforcement Of Its Intellectual Property Rights.

69. Pfizer has a long history and orchestrated program of vigorously enforcing its patents against generic ANDA applicants, including Apotex Inc.

70. For example, Pfizer has sued ANDA-filers for alleged infringement of patents purportedly covering its blockbuster drugs Accupril®, Norvasc®, Neurontin® and Detrol®. *See, e.g., Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, No. 99-cv-922-DRD (D.N.J.); *Pfizer Inc. v. Teva Pharms. USA, Inc.*, No. 05-cv-620-DRD (D.N.J.); *Pfizer Inc. v. Apotex, Inc.*, No. 03-cv-5289 (N.D. Ill.); *Warner Lambert Co. v. Apotex Corp.*, No. 98-cv-4293 (N.D. Ill.); *Pfizer Inc. v. IVAX Pharms., Inc.*, No. 07-cv-174-DMC (D.N.J.).

71. Pfizer also has filed patent infringement suits against Apotex regarding its drugs Norvasc® and Neurontin®. *See, e.g., Pfizer Inc. v. Apotex Inc.*, No. 03-cv-5289 (N.D. Ill.); *Warner Lambert Co. v. Apotex Corp.*, No. 98-cv-4293 (N.D. Ill.).

VIII. Atorvastatin Litigation And Pfizer's Enforcement Of The '995 Patent.

72. Pfizer has further demonstrated a willingness and intention to enforce the '995 patent against similarly-situated generic pharmaceutical companies that have filed an ANDA to market generic atorvastatin.

73. In particular, Pfizer filed suit against at least the following of Apotex's competitors:

- Ranbaxy, in *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, No. 03-cv-209-JJF (D. Del.);
- Teva, in *Pfizer Inc. v. Teva Pharms. USA Inc.*, No. 07-cv-360-JJF (D. Del.);
- Cobalt, in *Pfizer Inc. v. Cobalt Pharms., Inc.*, No. 07-cv-790-JJF (D. Del.).

IX. There Is A Substantial And Continuing Justiciable Controversy Between Apotex And Pfizer Regarding Infringement And Validity Of The Patents-In-Suit.

74. By suing Apotex and others for infringement of the '995 patent, Pfizer has already created case or controversy jurisdiction under 35 U.S.C. § 271(e)(2) and Article III of the Constitution for any declaratory judgment action as to the '995 patent. There is a substantial and continuing justiciable controversy between Apotex and Pfizer regarding infringement and validity of the '104, '156, and '971 patents as well.

75. By preparing and filing Apotex Inc.'s ANDA, Apotex Inc. has substantially prepared to make generic atorvastatin tablets.

76. By submitting its ANDA and filing a paragraph IV certification to the patents-in-suit, Apotex Inc. has committed a so-called or alleged artificial act of infringement sufficient to create case or controversy jurisdiction under 35 U.S.C. § 271(e)(2) and Article III of the Constitution.

77. By submitting the patents-in-suit to the FDA for listing in the Orange Book, Pfizer has affirmatively represented to the world, including Apotex Inc., that "a claim of patent

infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2). In other words, Pfizer necessarily maintains that an infringement claim on the patents-in-suit could be reasonably asserted against Apotex.

78. Pfizer did not sue Apotex for infringement of the '104, '156, and '971 patents within 45 days of receipt of Apotex Inc.'s notice of paragraph IV certification. In compliance with 21 U.S.C. § 355(j)(5)(C), Apotex Inc. granted Pfizer an Offer of Confidential Access to Apotex Inc.'s ANDA for generic atorvastatin tablets. As such, Apotex Inc. is statutorily entitled to institute—and this Court has constitutional authority to adjudicate—a declaratory judgment action against Pfizer. 35 U.S.C. § 271(e)(5).

79. Pfizer has demonstrated a willingness and, further, an intention to enforce its LIPITOR® patents against similarly-situated atorvastatin ANDA-filers.

80. Pfizer's listing of the '104, '156, and '971 patents and Apotex Inc.'s paragraph IV certification satisfy Article III of the Constitution by creating the necessary case or controversy between Pfizer and Apotex regarding infringement and validity of those patents.

81. Furthermore, based upon, *inter alia*, the listing of the patents-in-suit and Pfizer's necessary assertion that an infringement claim could be brought against any generic atorvastatin applicant; Apotex Inc.'s ANDA with a paragraph IV certification; Apotex Inc.'s intention to seek approval for its generic atorvastatin product before expiration of the patents-in-suit; Pfizer's suit against Apotex for infringement of the '995 patent; Pfizer's suits against similarly-situated third-parties concerning the '995 patent; Pfizer's pattern of aggressively enforcing its patents against Apotex, specifically, and the generic pharmaceutical industry, generally, there is a continuing

case or controversy between Apotex and Pfizer regarding infringement and validity of the patents-in-suit.

82. These facts alone give rise to a substantial and continuing case or controversy under Article III of the Constitution over which this Court has subject matter jurisdiction.

83. Based on these same facts, Apotex is under a reasonable apprehension that Pfizer will sue Apotex alleging infringement of the '104, '156, and '971 patents. Such a reasonable apprehension creates an actual case or controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

84. Absent a declaratory judgment from this Court, approval of Apotex Inc.'s ANDA will also be indefinitely delayed by any 180-day generic marketing exclusivity associated with the '104, '156, and '971 patents. This delay also injures Apotex and creates an actual case or controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

85. Apotex is statutorily entitled to file and maintain this declaratory judgment action against Pfizer pursuant to the MMA in order to obtain patent certainty, and to clear up any generic exclusivity bottlenecks necessary to obtain approval of Apotex Inc.'s ANDA.

86. To avoid legal uncertainty, to protect its substantial investment, to protect its anticipated future investments in its manufacturing process for Apotex Inc.'s generic atorvastatin tablets, and to open the generic atorvastatin market, Apotex has instituted this action and is entitled to a declaration of the rights of the parties with respect to the patents-in-suit.

COUNT I
(Declaratory Judgment of Non-Infringement of the '995 Patent)

87. Apotex adopts by reference, repeats, and realleges its averments in paragraphs 1-86 above as if fully set forth herein.

88. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Pfizer regarding, *inter alia*, non-infringement of the '995 patent.

89. The manufacture, use, sale, offer for sale, or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if made, imported or marketed, infringe any valid and/or enforceable claim of the '995 patent.

90. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '995 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '995 Patent)

91. Apotex adopts by reference, repeats, and realleges its averments in paragraphs 1-90 above as if fully set forth herein.

92. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Pfizer regarding, *inter alia*, the validity of the '995 patent.

93. The claims of the '995 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

94. Apotex is entitled to a judicial declaration that the claims of the '995 patent are invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the '104 Patent)

95. Apotex adopts by reference, repeats, and realleges its averments in paragraphs 1-94 above as if fully set forth herein.

96. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Pfizer regarding, *inter alia*, non-infringement of the '104 patent.

97. The manufacture, use, sale, offer for sale, or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if made, imported or marketed, infringe any valid and/or enforceable claim of the '104 patent.

98. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '104 patent.

COUNT IV
(Declaratory Judgment of Invalidity of the '104 Patent)

99. Apotex adopts by reference, repeats, and realleges its averments in paragraphs 1-98 above as if fully set forth herein.

100. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Pfizer regarding, *inter alia*, the invalidity of the '104 patent.

101. The claims of the '104 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

102. Apotex is entitled to a judicial declaration that the claims of the '104 patent are invalid.

COUNT V
(Declaratory Judgment of Non-Infringement of the '156 Patent)

103. Apotex adopts by reference, repeats, and realleges its averments in paragraphs 1-102 above as if fully set forth herein.

104. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Pfizer regarding, *inter alia*, non-infringement of the '156 patent.

105. The manufacture, use, sale, offer for sale, or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if made, imported or marketed, infringe any valid and/or enforceable claim of the '156 patent.

106. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '156 patent.

COUNT VI
(Declaratory Judgment of Invalidity of the '156 Patent)

107. Apotex adopts by reference, repeats, and realleges its averments in paragraphs 1-106 above as if fully set forth herein.

108. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Pfizer regarding, *inter alia*, the invalidity of the '156 patent.

109. The claims of the '156 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

110. Apotex is entitled to a judicial declaration that the claims of the '156 patent are invalid.

COUNT VII
(Declaratory Judgment of Non-Infringement of the '971 Patent)

111. Apotex adopts by reference, repeats, and realleges its averments in paragraphs 1-110 above as if fully set forth herein.

112. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Pfizer regarding, *inter alia*, non-infringement of the '971 patent.

113. The manufacture, use, sale, offer for sale, or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if made, imported or marketed, infringe any valid and/or enforceable claim of the '971 patent.

114. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '971 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of the '971 Patent)

115. Apotex adopts by reference, repeats, and realleges its averments in paragraphs 1-114 above as if fully set forth herein.

116. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Pfizer regarding, *inter alia*, the validity of the '971 patent.

117. The claims of the '971 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

118. Apotex is entitled to a judicial declaration that the claims of the '971 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counterclaim-Plaintiff Apotex respectfully prays for judgment in its favor and against Plaintiff/Counterclaim-Defendant Pfizer:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '995 patent;

(b) Declaring that the claims of the '995 patent are invalid;

(c) Declaring that the manufacture, use, sale, offer for sale, or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '104 patent;

(d) Declaring that the claims of the '104 patent are invalid;

(e) Declaring that the manufacture, use, sale, offer for sale, or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '156 patent;

(f) Declaring that the claims of the '156 patent are invalid;

(g) Declaring that the manufacture, use, sale, offer for sale, or importation of the atorvastatin product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '971 patent;

(h) Declaring that the claims of the '971 patent are invalid;

(i) Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Apotex;

(j) Declaring this case exceptional and awarding Apotex its reasonable attorney fees and costs of this Counterclaim under 35 U.S.C. § 285; and

(k) Awarding Apotex such other and further relief as the Court may deem just and proper.

JURY DEMAND

Apotex Inc. and Apotex Corp. hereby demand a trial by jury as to all issues so triable.

Dated: February 9, 2009.

Respectfully submitted,

APOTEX INC. AND APOTEX CORP.

By: */s/ Andrew M. Alul*

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Attorney for Defendants
Apotex Inc. and Apotex Corp.

CERTIFICATE OF SERVICE

I, Andrew M. Alul, an attorney, hereby certify that on this 9th day of February, 2009, a true and correct copy of the foregoing ANSWER, DEFENSES, COUNTERCLAIM AND JURY DEMAND OF DEFENDANTS APOTEX INC. AND APOTEX CORP. was filed with the Clerk of the Court using the Electronic Case Filing (ECF) system which will send notification of such filing via electronic mail to all counsel of record.

/s/ Andrew M. Alul

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